Infusion set Product Recall 11 09 17

Consumers and healthcare professionals are advised that Medtronic, in consultation with the TGA, is initiating a recall for specific lot numbers of infusion sets used with all models of Medtronic insulin pumps. The recall is related to a certain discontinued component in these infusion sets and does not include insulin pumps or glucose sensors.

A component, the vent membrane, in the recalled infusion sets may be susceptible to being blocked by fluid during the process of priming/fill-tubing. This situation can lead to potential over-delivery of insulin shortly after an infusion set change, which may cause hypoglycaemia. Currently manufactured infusion sets, available to patients since April 2017, include a design update of this component which the company believes reduces the risk of insulin over-delivery after an infusion set change.

Australian customers can easily determine if they have recalled infusion sets by entering the lot number at https://checklots.medtronicdiabetes.com. People without internet access should call the Global Help Line [1800 777 808] and press option 1. Medtronic will replace recalled infusion sets at no cost.

Please do not use recalled infusion sets. Use only infusion sets made with the new and enhanced membrane starting with the next set change. Medtronic is also reminding customers that it is very important to carefully follow the instructions for use regarding the priming/fill-tubing process.

If you have any questions or concerns about this issue, please see https://www.medtronic-diabetes.com.au/customer-support/safety-information